# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **SCHEDULE 13G**

**Under the Securities Exchange Act of 1934** 

# EDAP TMS S.A.

(Name of Issuer)

American Depositary Shares and Ordinary Shares, nominal value €0.13 per share

(Title of Class of Securities)

## 268311107\*\*

(CUSIP Number)

October 28, 2019

(Date of Event Which Requires Filing of this Statement)

Check the appropriate box to designate the rule pursuant to which this Schedule is filed:

[] Rule 13d-1(b)

[X] Rule 13d-1(c)

[] Rule 13d-1(d)

\* The remainder of this cover page shall be filled out for a reporting person's initial filing on this form with respect to the subject class of securities, and for any subsequent amendment containing information which would alter the disclosures provided in a prior cover page.

\*\* There is no CUSIP number assigned to the Ordinary Shares. CUSIP number 268311107 has been assigned to the American Depositary Shares of the Company, which are quoted on the Nasdaq Global Market under the symbol "EDAP." Each American Depositary Share represents 1 Ordinary Share.

The information required in the remainder of this cover page shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934 ("Act") or otherwise subject to the liabilities of that section of the Act but shall be subject to all other provisions of the Act (however, see the Notes).

NAMES OF REPORTINC PERSONS Opaleye Management Inc.         1       I.R.S. IDENTIFICATION NOS. OF ABOVE PERSONS (ENTITIES ONLY) 20-5648736         CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP (SEE INSTRUCTIONS)         (a)       []         2       (b)         (b)       []         SEC USE ONLY         3       CITIZENSHIP OR PLACE OF ORGANIZATION         4       Massachusetts         5       0         VUMBER OF SHARES       SOLE VOTING POWER         5       0         SHARED VOTING POWER         6       1,520,500 Ordinary Shares, nominal value 60.13 per share ("Ordinary Shares") (represented by 1,520,500 American Depositary Shares ("ADS"))         SHARED DISPOSITIVE POWER         8       1,520,500 Ordinary Shares (represented by 1,520,500 ADS)         9       1,520,500 Ordinary Shares (represented by 1,520,500 ADS)         CHECK IF THE AGGREGATE AMOUNT IN ROW (9) EXCLUDES CERTAIN SHARES (SEE INSTRUCTIONS)         10       []         PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (9)         12       CO									
1       I.R.S. IDENTIFICATION NOS. OF ABOVE PERSONS (ENTITIES ONLY)         2       (b) []         2       (b) []         3       CTTIZENSHIP OR PLACE OF ORGANIZATION         4       Massachusetts         5       0         NUMBER OF SHARES       SOLE VOTING POWER         5       0         SHARED VOTING POWER         5       0         SOLE VOTING POWER         SHARES         SUBSECTION INFORMATION         4       Massachusetts         5       0         SHARED VOTING POWER         SHARED VOTING POWER         SHARED VOTING POWER         SHARES         BENEFICIALLY         6       1,520,500 Ordinary Shares, nominal value €0.13 per share ("Ordinary Shares") (represented by 1,520,500 American Depositary Shares ("ADS"))         BY EACH       SOLE DISPOSITIVE POWER         REPORTING       7         9       1,520,500 Ordinary Shares (represented by 1,520,500 ADS)         AGGREGATE AMOUNT IN ROW (9) EXCLUDES CERTAIN SHARES (SEE INSTRUCTIONS)         10       1         9       1,520,500 Ordinary Shares (represented by 1,520,500 ADS)         CHECK IF THE AGGREGATE AMOUNT IN ROW (9) EXCLUDES CERTAIN SHARES (SEE INSTRUCTIONS)									
20-5648796         CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP (SEE INSTRUCTIONS)         (a)       []         (b)       []         SEC USE ONLY         3         CITIZENSHIP OR PLACE OF ORGANIZATION         4       Massachusetts         SOLE VOTING POWER         5       0         NUMBER OF SHARES         SALE VOTING POWER         SHARED VOTING POWER         SHARED VOTING POWER         SHARED VOTING POWER         SHARED VOTING POWER         SHARES (* JDS'')         SHARED DISPOSITIVE POWER         SOLE DISPOSITIVE POWER         REPORTING         7       0         SHARED DISPOSITIVE POWER         1,520,500 Ordinary Shares (represented by 1,520,500 ADS)       1         AGGREGATE AMOUNT BENETICIALLY OWNED BY EACH REPORTING PERSON         9       1,520,500 Ordinary Shares (represented by 1,520,500 ADS)       1         CHECK IF THE AGGREGATE AMOUNT IN ROW (9)         SUBMERICIALLY OWNED BY EACH REPORTING PERSON         9       1,520,500 Ordinary Shares (represented by 1,520,500		Opaleye	Opaleye Management Inc.						
20-5648796         CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP (SEE INSTRUCTIONS)         (a)       []         (b)       []         SEC USE ONLY         3         CITIZENSHIP OR PLACE OF ORGANIZATION         4       Massachusetts         SOLE VOTING POWER         5       0         NUMBER OF         SHARED VOTING POWER         SHARES ESUSON Ordinary Shares, nominal value €0.13 per share ("Ordinary Shares") (represented by 1,520,500 American Depositary Shares ("ADS"))         BY EACH         REPORTING         PERSON WITH:       7         0       SHARED DISPOSITIVE POWER         1,520,500 Ordinary Shares (represented by 1,520,500 ADS)       1         AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON         9       1,520,500 Ordinary Shares (represented by 1,520,500 ADS)       1         CHECK IF THE AGGREGATE AMOUNT IN ROW (9)         SECENT OF CLASS REPRESENTED BY AMOUNT IN ROW (9)         SL24% *	1	IRSI	DENTIF	ENTIEL ATION NOS DE ADOVE DEDSONS (ENTITIES ONI V)					
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NUMBER OF SHARES BENEFICIALLY OWNED BY EACH REPORTING PERSON WITH:       SOLE VOTING POWER SHARES ("ADS"))         9       1,520,500 Ordinary Shares, nominal value €0.13 per share ("Ordinary Shares") (represented by 1,520,500 American Depositary Shares ("ADS"))         8       1,520,500 Ordinary Shares (represented by 1,520,500 ADS)         9       1,520,500 Ordinary Shares (represented by 1,520,500 ADS)         9       1,520,500 Ordinary Shares (represented by 1,520,500 ADS)         10       []         PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (9)         5.24% *         TYPE OF REPORTING PERSON (SEE INSTRUCTIONS)									
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NUMBER OF SHARES       SHARED VOTING POWER         BENEFICIALLY OWNED       6         1,520,500 Ordinary Shares, nominal value €0.13 per share ("Ordinary Shares") (represented by 1,520,500 American Depositary Shares ("ADS"))         BY EACH REPORTING PERSON WITH:       50LE DISPOSITIVE POWER         8       SHARED DISPOSITIVE POWER         8       1,520,500 Ordinary Shares (represented by 1,520,500 ADS)         AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON         9       1,520,500 Ordinary Shares (represented by 1,520,500 ADS)         CHECK IF THE AGGREGATE AMOUNT IN ROW (9) EXCLUDES CERTAIN SHARES (SEE INSTRUCTIONS)         10       []         PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (9)         5.24% *         TYPE OF REPORTING PERSON (SEE INSTRUCTIONS)				SOLE VOTING POWER					
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BENEFICIALLY OWNED BY EACH REPORTING       6       1,520,500 Ordinary Shares, nominal value €0.13 per share ("Ordinary Shares") (represented by 1,520,500 American Depositary Shares ("ADS"))         BY EACH REPORTING       SOLE DISPOSITIVE POWER         7       0         8       1,520,500 Ordinary Shares (represented by 1,520,500 ADS)         AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON         9       1,520,500 Ordinary Shares (represented by 1,520,500 ADS)         CHECK IF THE AGGREGATE AMOUNT IN ROW (9) EXCLUDES CERTAIN SHARES (SEE INSTRUCTIONS)         10       []         PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (9)         5.24% *         TYPE OF REPORTING PERSON (SEE INSTRUCTIONS)	NUMB	ER OF		SHARED VOTING POWER					
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PERSON WITH:       7       0         SHARED DISPOSITIVE POWER       SHARED DISPOSITIVE POWER         8       1,520,500 Ordinary Shares (represented by 1,520,500 ADS)         9       1,520,500 Ordinary Shares (represented by 1,520,500 ADS)         CHECK IF THE AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON         10       []         PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (9)         5.24% *         TYPE OF REPORTING PERSON (SEE INSTRUCTIONS)									
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AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON         9       1,520,500 Ordinary Shares (represented by 1,520,500 ADS)         CHECK IF THE AGGREGATE AMOUNT IN ROW (9) EXCLUDES CERTAIN SHARES (SEE INSTRUCTIONS)         10       []         PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (9)         11       5.24% *         TYPE OF REPORTING PERSON (SEE INSTRUCTIONS)				SHARED DISPOSITIVE POWER					
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CHECK IF THE AGGREGATE AMOUNT IN ROW (9) EXCLUDES CERTAIN SHARES (SEE INSTRUCTIONS)         10       []         PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (9)         11       5.24% *         TYPE OF REPORTING PERSON (SEE INSTRUCTIONS)									
CHECK IF THE AGGREGATE AMOUNT IN ROW (9) EXCLUDES CERTAIN SHARES (SEE INSTRUCTIONS)         10       []         PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (9)         11       5.24% *         TYPE OF REPORTING PERSON (SEE INSTRUCTIONS)	q	1 520 500 Ordinary Shares (represented by 1 520 500 ADS)							
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11     5.24% *       TYPE OF REPORTING PERSON (SEE INSTRUCTIONS)	10								
TYPE OF REPORTING PERSON (SEE INSTRUCTIONS)		PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (9)							
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12 CO		TYPE OF REPORTING PERSON (SEE INSTRUCTIONS)							
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	12	30							

	NAMES OF REPORTING PERSONS							
	I.R.S. I	I.R.S. IDENTIFICATION NOS. OF ABOVE PERSONS (ENTITIES ONLY)						
1	Onaley							
	Opaleye, L.P. CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP (SEE INSTRUCTIONS)							
2	(a) [ ] (b) [ ]							
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			SOLE VOTING POWER					
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OWNED BY EACH			SOLE DISPOSITIVE POWER					
REPOR		7	0					
PERSON	N WITH:		SHARED DISPOSITIVE POWER					
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11	5.24% *							
	TYPE OF REPORTING PERSON (SEE INSTRUCTIONS)							
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NAMES OF REPORTING PERSONS I.R.S. IDENTIFICATION NOS. OF ABOVE PERSONS (ENTITIES ONLY)								
1								
	James Silverman							
	CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP (SEE INSTRUCTIONS)							
	(a) [ ]	1						
2	(a) [ ]							
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3	CITIZE	ENSHIP	OR PLACE OF ORGANIZATION					
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NUMBI	-		SHARED VOTING POWER					
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PERSON	-	7	0					
			SHARED DISPOSITIVE POWER					
		8	1,520,500 Ordinary Shares (represented by 1,520,500 ADS)					
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9	1,520,500 Ordinary Shares (represented by 1,520,500 ADS) CHECK IF THE AGGREGATE AMOUNT IN ROW (9) EXCLUDES CERTAIN SHARES (SEE INSTRUCTIONS)							
10	[]							
	PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (9)							
11	5.24% *							
	TYPE OF REPORTING PERSON (SEE INSTRUCTIONS)							
12	IN							
14	111							

#### Item 1(a). Name of Issuer:

The name of the issuer is EDAP TMS S.A. (the "Company").

### Item 1(b). Address of Issuer's Principal Executive Offices:

The Company's principal executive offices are located at Parc Activite La Poudrette Lamartine, 4/6 Rue du Dauphine, 69120 Vaulx-en-Velin, France.

#### Item 2(a). Name of Person Filing.

This statement is filed by the entities and persons listed below, who are collectively referred to herein as "<u>Reporting Persons</u>" with respect to the Ordinary Shares of the Company:

#### **Opaleye** Fund

Opaleye, L.P. (the "<u>Opaleye Fund</u>"), a private fund formed in the state of Delaware.

#### **Investment Manager**

Opaleye Management Inc. (the "<u>Investment Manager</u>"), with respect to the Ordinary Shares held by the Opaleye Fund, a private fund to which the Investment Manager serves as investment manager. The Investment Manager also serves as a portfolio manager for a separate managed account (the "<u>Managed Account</u>") and may be deemed to indirectly beneficially own securities owned by the Managed Account. The Investment Manager disclaims beneficial ownership of the shares held by the Managed Account.

### **Reporting** Individual

Mr. James Silverman (the "<u>Reporting Individual</u>"), with respect to the Ordinary Shares held by the Opaleye Fund. Mr. Silverman is the President of the Investment Manager.

#### Item 2(b). Address of Principal Business Office or, if None, Residence.

One Boston Place, 26<sup>th</sup> Floor Boston, Massachusetts 02108

#### Item 2(c). Citizenship.

Citizenship is set forth in Row 4 of the cover page for each Reporting Person and is incorporated herein by reference for each such Reporting Person.

#### Item 2(d). Title of Class of Securities.

Ordinary Shares, nominal value  $\notin 0.13$  per share ("<u>Ordinary Shares</u>") represented by American Depositary Shares ("<u>ADS</u>"), each of which represents one Ordinary Share.

#### Item 2(e). CUSIP Number.

There is no CUSIP number assigned to the Ordinary Shares. CUSIP number 268311107 has been assigned to the ADS, which are quoted on the Nasdaq Global Market under the symbol "EDAP".

Item 3. If This Statement is Filed Pursuant to Rule 13d-1(b), or 13d-2(b) or (c), Check Whether the Person Filing is a:

(a)	[]	Broker or dealer registered under Section 15 of the Exchange Act.
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- (b) [] Bank as defined in Section 3(a)(6) of the Exchange Act.
- (c) [] Insurance company as defined in Section 3(a)(19) of the Exchange Act.
- (d) [] Investment company registered under Section 8 of the Investment Company Act.
- (e) [] An investment adviser in accordance with Rule 13d-1(b)(1)(ii)(E);
- (f) [] An employee benefit plan or endowment fund in accordance with Rule 13d-1(b)(1)(ii)(F);
- (g) [] A parent holding company or control person in accordance with Rule 13d-1(b)(1)(ii)(G);
- (h) [] A savings association as defined in Section 3(b) of the Federal Deposit Insurance Act;
- (i) [] A church plan that is excluded from the definition of an investment company under Section 3(c)(14) of the Investment Company Act;
- (j) [] A non-U.S. institution in accordance with Rule 13d-1(b)(1)(ii)(J);
- (k) [] Group, in accordance with Rule 13d-1(b)(1)(ii)(K).

If filing as a non-U.S. institution in accordance with Rule 13d-1(b)(1)(ii)(J), please specify the type of institution:

### Item 4. Ownership.

(a) Amount beneficially owned:

Opaleye Management Inc. — 1,520,500 Ordinary Shares (represented by 1,520,500 ADS)\* Opaleye, L.P. — 1,520,500 Ordinary Shares (represented by 1,520,500 ADS)\* James Silverman — 1,520,500 Ordinary Shares (represented by 1,520,500 ADS)\*

\* Includes 49,500 Ordinary Shares (represented by 49,500 ADS) held by the Managed Account

(b) Percent of class:

Opaleye Management Inc. — 5.24%\*\* Opaleye, L.P. — 5.24%\*\* James Silverman — 5.24%\*\*

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- (c) Number of shares as to which the person has:
  - (i) Sole power to vote or to direct the vote:

Opaleye Management Inc. — 0 Ordinary Shares Opaleye, L.P. — 0 Ordinary Shares James Silverman — 0 Ordinary Shares

(ii) Shared power to vote or to direct the vote:

Opaleye Management Inc. — 1,520,500 Ordinary Shares (represented by 1,520,500 ADS)\* Opaleye, L.P. — 1,520,500 Ordinary Shares (represented by 1,520,500 ADS)\* James Silverman — 1,520,500 Ordinary Shares (represented by 1,520,500 ADS)\*

- \* Includes 49,500 Ordinary Shares (represented by 49,500 ADS) held by the Managed Account
  - (iii) Sole power to dispose or to direct the disposition of:

Opaleye Management Inc. — 0 Ordinary Shares Opaleye, L.P. — 0 Ordinary Shares James Silverman — 0 Ordinary Shares

(iv) Shared power to dispose or to direct the disposition of:

Opaleye Management Inc. — 1,520,500 Ordinary Shares (represented by 1,520,500 ADS)\* Opaleye, L.P. — 1,520,500 Ordinary Shares (represented by 1,520,500 ADS)\* James Silverman — 1,520,500 Ordinary Shares (represented by 1,520,500 ADS)\*

\* Includes 49,500 Ordinary Shares (represented by 49,500 ADS) held by the Managed Account

#### Item 5. Ownership of Five Percent or Less of a Class.

If this statement is being filed to report the fact that as of the date hereof the Reporting Persons have ceased to be the beneficial owners of more than five percent of the class of securities, check the following [].

#### Item 6. Ownership of More than Five Percent on Behalf of Another Person.

Not applicable.

Item 7. Identification and Classification of the Subsidiary Which Acquired the Security Being Reported by the Parent Holding Company or Control Person.

Not applicable.

## Item 8. Identification and Classification of Members of the Group.

Not applicable.

### Item 9. Notice of Dissolution of Group.

Not applicable.

## Item 10. Certification.

By signing below I certify that, to the best of my knowledge and belief, the securities referred to above were not acquired and are not held for the purpose of or with the effect of changing or influencing the control of the issuer of the securities and were not acquired and are not held in connection with or as a participant in any transaction having that purpose or effect.

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## SIGNATURE

After reasonable inquiry and to the best of my knowledge and belief, I certify that the information set forth in this statement is true, complete and correct.

Date: November 7, 2019	By: /s/ James Silverman
	James Silverman
	Opaleye, L.P.
Date:November 7, 2019	By: /s/ James Silverman
	Name: James Silverman
	Title: Managing Member of Opaleye GP LLC,
	the General Partner of Opaleye, L.P.
	Opaleye Management Inc.
Date: November 7, 2019	By: /s/ James Silverman
	Name: James Silverman
	Title: President

#### JOINT FILING AGREEMENT

This Joint Filing Agreement, dated November 7, 2019, is entered into by and among Opaleye Management Inc., a Massachusetts corporation, Opaleye, L.P., a Delaware limited partnership and James Silverman, an individual (collectively referred to herein as (the "Filers"). Each of the Filers may be required to file with the U.S. Securities and Exchange Commission a statement on Schedule 13G with respect to the Ordinary Shares (represented by ADS, each of which represents one Ordinary Share) of the Issuer beneficially owned by them from time to time. Pursuant to and in accordance with Rule 13(d)(1)(k) promulgated under the Securities Exchange Act of 1934, as amended, the Filers hereby agree to file a single statement on Schedule 13G and/or 13D (and any amendments thereto) on behalf of each of such parties, and hereby further agree to file this Joint Filing Agreement as an exhibit to such statement, as required by such rule. This Joint Filing Agreement may be terminated by any of the Filers upon one week's prior written notice or such lesser period of notice as the Filers may mutually agree.

DATED: November 7, 2019

By: /s/ James Silverman James Silverman

Opaleye, L.P.

By: /s/ James Silverman

Name: James Silverman

Title: Managing Member of Opaleye GP LLC, the General Partner of Opaleye, L.P.

Opaleye Management Inc.

By: /s/ James Silverman

Name: James Silverman Title: President